JAN 17 2003

RICHARD WOLF
Medical Instruments Corporation

353 Corporate Woods Parkway
Vernon Hills, IL 60061
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Customer Service: 800-323-WOLF
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K023813

12.0 510 (k) Summary of Safety and Effectiveness

			Date of Preparation: **November 11, 2002**
Company / Institution name: **RICHARD WOLF MEDICAL INSTRUMENTS CORP.**			FDA establishment registration number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913 1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913 0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP / Postal Code: IL 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:

Trade name: Bipolar Forceps	Model number: XXXX
Common name: Bipolar Forceps	Classification name: DEVICE, ELECTROSURGICAL, CUTTING & COAGULATION & ASSESSORIES

Information on devices to which substantial equivalence is claimed: same devices as cleared devices

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K012279	1 Patton Tripol Bipolar Forceps	1
	2	2
3	3	3
4	4	4
5	5	5

1.0 Description

The submitted Bipolar forceps are forceps that grasps, coagulate, and transects tissue, utilizing electrical current. The Bipolar forceps are compatible with all standard bipolar generators that have a bipolar outlet.

2.0 Intended Use

The submitted device is intended for use in open and laparoscopic surgery where grasping, coagulating, and transecting is indicated.

3.0 Technological Characteristics

The submitted devices are the same devices cleared in 510(k) K012279, April 30, 2002.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the existing devices. The submitted devices are the same devices cleared in 510(k) K012279, April 30, 2002.

5.0 Performance Data

The submitted devices perform the same as the devices cleared in 510(k) K012279, April 30, 2002 by Patton Medical Corporation.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness, when used according to the instructions manual.

By: Robert L. Casarsa Date: Nov 11, 2002

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2003

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corporation
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K023813
Trade Name: Bipolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Code: GEI
Dated: November 11, 2002
Received: November 15, 2002

Dear Mr. Casarsa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.0 INDICATIONS FOR USE

510(k) Number (if known): – K023813

Device Name: Bipolar Forceps

Indications For Use:

The Bipolar Forceps is intended for use in open and laparoscopic surgeries where grasping, coagulating, and transecting of tissue is indicated.

Indications and Application:

The submitted Bipolar Forceps are indicated for both GYN and general laparoscopic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023813

Prescription Use ✓ OR Over-The Counter _____
Per 21 CFR 801.109

(Optional Format 1'2-96)